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VACCINE INJURY COMPENSATION MECHANISM FOR ADVERSE EVENTS CAUSED BY COVID-19 VACCINES IN SOUTHEAST ASIAN COUNTRIES

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Abstract: Adverse Events Following Immunization (AEFI) or vaccine injury is an issue of great concern in many nations, including Malaysia. This issue has long attracted the public's interest, but the emergence of COVID-19 disease has triggered greater interest as nations engaged in mass vaccination programs for their citizens. This is further exacerbated by the growing dissatisfaction with the traditional tort litigation system which necessitates exploring alternative ways to deal with vaccine injury cases. While the vaccine injury compensation program (VICP) has been implemented in several countries to compensate affected individuals following vaccination, not all VICP can cater to public health emergencies, especially regarding vaccine COVID-19. Malaysia, for example, has a similar program known as Special Financial Assistance Adverse Effects of COVID-19 Vaccine (SFA), which allows individuals to receive financial assistance if they suffer from AEFI of COVID-19. Thus, this paper is intended to review and analyse the VICP in Southeast Asian countries and its implementation in Malaysia. It is important to explore these VICP to strengthen the existing processes in terms of accountability and compensation. This qualitative research was based on document review and comparative methodologies by exploring the VICP in Southeast Asia and similar mechanism in Malaysia to enrich the subject matter of the vaccine COVID-19 liability. The finding shows that the VICP program seems to be a great alternative in dealing with vaccine injury cases, especially in addressing the growing dissatisfaction with the traditional tort litigation system. Malaysia, Singapore, and Thailand has its own VICP for affected individuals with COVID-19 vaccines while Myanmar, Cambodia, Timor-Leste, Indonesia, Vietnam, and the Philippines are under COVID-19 vaccine injury compensation scheme by COVID-19 Vaccines Global Access (COVAX) offered in 92 low- and middle-income nations.

Keywords: COVID-19, vaccine injury, compensation, vaccine, VICP.

Introduction

Vaccination is the most effective and efficient way to combat contagious diseases and ensure the public's health. Vaccines have saved almost 386 million lives and prevented nearly 6 million deaths globally from various diseases, as of 2017 (Wilder-Smith *et al.,* 2017; Rodrigues & Plotkin, 2020). However, there is still a hesitancy to vaccinate due to the raising concerns about vaccine safety (Feng & LI, 2021). Regardless of how detailed the pre-clinical studies in animals and clinical trials in patients are certain undesirable effects may not be recognized until they affected a significant number of individuals (National Pharmaceutical Reglatory Agency (NPRA), 2016).

COVID-19 vaccines are approved through the Emergency Use Listing (EUL) procedure of the World Health Organization (WHO) that has the authority to determine if new health items are suitable for use in public health emergencies (WHO, 2021c). Adverse event following immunization (AEFI) refers to the undesirable medical incident that occurs after vaccination and does not necessarily have a causal relationship with a vaccine (WHO, 2021a). As

an example, in the COVID-19 vaccination, rare blood clotting is identified as severe AEFI as it may lead to fatality (Mahase, 2021; Wise, 2021).

In the Malaysian context, 76.1% (24.8 million) of the population have been fully vaccinated for COVID-19, with more than 49 million doses being administrated as of November 2021 (COVIDNOW, 2021). Based on the report of serious AEFI by the brand of the vaccines (Comirnaty, CoronaVac, AstraZeneca, Convidecia, and Covilo), 1,652 or 6.9% of the total AEFI reports received were categorised as serious AEFIs and the reporting rate of serious AEFIs was recorded at 0.03 per 1,000 doses (NPRA, 2021). In the Malaysian context, AEFI, including those of the COVID-19 vaccines, is reported to the National Pharmaceutical Regulatory Agency (NPRA). As shown in Figure 1, serious AEFI of COVID-19 vaccines may be reported by submitting a form or email.

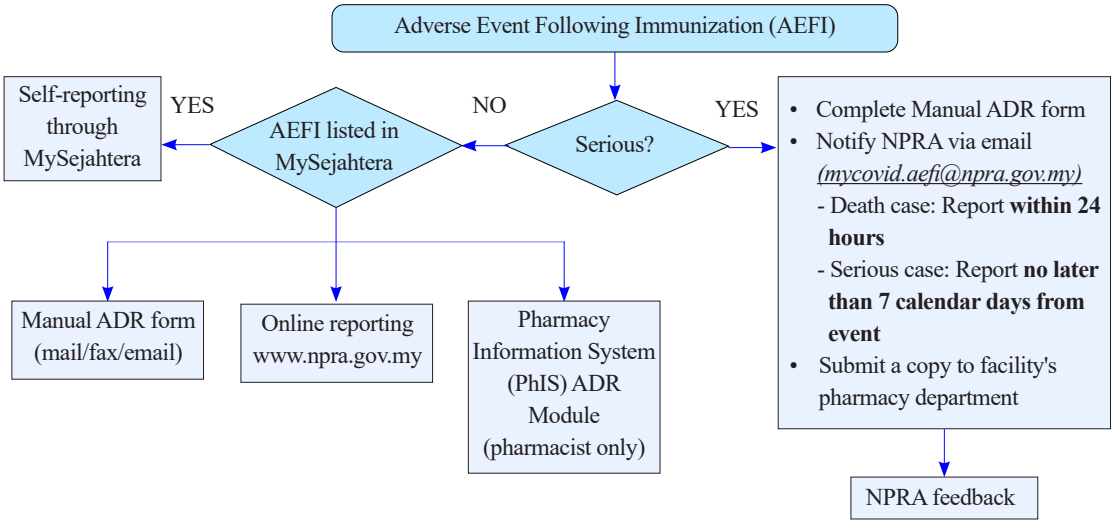

Figure 1: Reporting of Adverse Event Following Immunization (AEFI), Clinical Guidelines on COVID-19 Vaccination in Malaysia (MOH, 2021a)

Vaccination exposes recipients to the possibility of infrequent but severe side effects, raising essential considerations about vaccine manufacturers' liability and accountability. Hence, vaccine injury compensation programs (VICP) have been introduced in various countries to compensate persons who suffer side effects or injury after being administered with vaccines (Mungwira *et al*., 2020). The VICP was established as an alternative to the standard civil law system for addressing vaccine injury claims. It was supposed to be a no-fault claim procedure where the claimant must show that the vaccination caused the harm rather than that the injury was caused by medical negligence (Henry *et al*., 2015).

The Malaysian government has initiated a special financial aid for Malaysian citizens who experience significant adverse effects upon receiving the COVID-19 vaccine under the Program Imunisasi COVID-19 Kebangsaan (PICK). The Special Financial Assistance Adverse Effects of COVID-19 Vaccine (SFA) was initiated on March 22, 2021 for financial assistance in relation to severe AEFI of COVID-19 vaccines. Those eligible must apply to the Ministry of Health of Malaysia (MOH) for the SFA (NADMA, 2021). The compensation evaluation process involves the National Pharmaceutical Regulatory Agency (NPRA), COVID-19 Vaccine Special Pharmacovigilance Committee (JFK), Medical Technical Committee (JTP), Financial Special Assistance Advisory for

COVID-19 Vaccine Harmful Impact Committee and Agensi Pengurusan Bencana Negara (NADMA).

This programme provides individuals who suffer AEFI an avenue to seek financial assistance through the adversary system in Malaysia. Much research has been carried out on fault-based and non-fault-based compensation mechanisms; however, little has discussed about VICP, especially resemblance-like claims. The SFA is the first financial assistance for vaccine injury recipients in Malaysia, yet it has not been mentioned in other studies (Errico *et al.,* 2021), and there is much uncertainty surrounding the program's implementation, particularly in relation to its effectiveness given that a small number of people with serious AEFI have filed claims and it can be challenging to prove the causal link between the vaccines and the injury. Thus, this paper explores and evaluates the VICP in other Southeast Asian countries and compare it with the SFA for COVID-19 in Malaysia and identify issues in its implementation.

This study employs qualitative methods using doctrinal and comparative methodologies to explore the VICP in Southeast Asia and the similar mechanism in Malaysia. Document analysis of journal articles and country laws that form the basis of COVID-19 vaccine injury liability for compensation were undertaken. The national legislations as well as mechanisms and procedures involved that were studied were from Singapore, Thailand, Myanmar, Cambodia, Timor-Leste, Indonesia, Vietnam, the Philippines and Malaysia.

Materials and Methods

This qualitative research is based on document review and comparative methodologies by exploring the VICP in Southeast Asia and similar mechanism in Malaysia to enrich the subject matter of the vaccine COVID-19 liability.

Results and Discussion

Global Landscape Vaccine Injury Liability

It is critical to resolve vaccine producers' liability issues which hinder attempts to create and distribute vaccines, in order to ensure a strong vaccine development program (Winter *et al*., 2021). An individual who has been injured as a result of the vaccine is entitled to compensation. Vaccine liability protection systems differ from one jurisdiction to another, ranging from non-existent to substantial to no-fault compensation program in others (Winter *et al*., 2021). Vaccine manufacturers are required to follow three types of product liability laws around the world; to ensure that they manufacture vaccines in accordance with current Good Manufacturing Practices (GMPs), not; to design vaccines in such a way that severe side effects are minimized to the fullest extent practicable without compromising their cost and utility, not; and to properly label vaccines such as the risks and benefits of the product (Halabi, 2021).

According to English law, the first system of liability is established by the negligence cause of action. Second, a person who experiences injury as a result of utilizing a pharmaceutical product may be able to recover damages through a breach of contract and the Consumer Protection Act of 1987 that establishes the third liability system (Goudkamp, 2018). When it comes to liability for damaged medicinal products, the first thing to consider is whether the drug that induced the side effect should be categorized as a defective product. Besides, certain factors such as the presence of subjects, damaging action, damage, and a causal link between destructive product and damage must be met to develop liability. Special assumptions, such as the existence of guilt, an increased risk of injury, a special link between the defendant and the responsible person are often necessary (Knol Radoja, 2019).

However, some governments, such as the United States and the United Kingdom, already have policies in place to protect pharmaceutical manufacturers and encourage them to produce vaccines (Vicky & Papadimitriou, 2019).

In the United States, the government and pharmaceutical manufacturers agreed to an indemnity of risk agreement in advance, which resulted in the United States government being named as a defendant in the vaccine-related lawsuits. In the end, the United States was identified as a defendant in over 1,000 lawsuits (Halabi, 2021). Therefore, the VICP is amendment to overcome this problem. VICP is a no-fault compensation system that has been established in several countries to recompense people who have been vaccinated for adverse effects after receiving vaccines that have been properly administered. The history of VICP started in 1961 in Germany when the Supreme Court ruled in the case of a vaccinated individual who was damaged by the administration of a smallpox vaccine. Hence, Germany became the first country to establish VICP. In the 1970s, reports of adverse outcomes following vaccination with diphtheria, tetanus, and whole-cell pertussis fuelled calls for no-fault compensation program in most states of the United States. Although many high-income nations have VICP (some dating back to the 1960s), other countries do not employ the same method (Thompson *et al*., 2020).

The nations that are most equipped with the necessary legislation and restitution mechanisms for consumer among Southeast Asian countries include Brunei Darussalam, Malaysia, Singapore, and Thailand (Galasintu & Loveera, 2021). The Part X of Consumer Protection Act 1999 (CPA 1999) in Malaysia provides for product liability which were based on the Consumer Protection Act of 1987 of the United Kingdom that adopts the European Product Liability Directives (85/374/EEC). Strict responsibility is a notion that is introduced in Part X. It imposes producer accountability for harm a consumer sustains as a result of a defective product. While the Malaysian Act relies on consumer the burden of proof, the Consumer Case Procedures Act 2012 (Zuryani *et al*., 2019) in Thailand (CCPA 2012) indicated that the burden of proof lies with medical professionals. The doctor must demonstrate that he acted with care in carrying out his duties and avoided endangering the patient considering that medical professionals provide medical services (Chatarin Phusae, 2018). The question arises for countries that do not produce vaccines or rely on imported vaccines: What are the plans for affected people? and is it viable for them to sue the vaccine manufacturer or a third party involved in vaccine supply or does the government bear the responsibility? Nonetheless, proof of causation between the vaccine and the damage is required in all of these forms of liability. It is maintained that scientific evidence plays an important role in resolving vaccine liability challenges and that a re-examination of this role is timely given the public's interest in the continuous availability and supply of COVID-19 vaccinations throughout the pandemic (Goldberg, 2022).

Table 1: Vaccine liability in some regions (Rajneri *et al*., 2018; Goudkamp, 2018; Galasintu & Loveera, 2021)

Country/Continents	Vaccine Liability
The United States of America	Law of Tort VICP Countermeasures Injury Compensation Program (CICP)
European Countries	Law of Tort Product liability VICP
The United Kingdom	Law of Tort Breach of contract Consumer Protection Act 1987 Vaccine Damage Payments Act 1979 (VICP)
Southeast Asia	Law of Tort Product liability VICP

No-Fault Based Vaccine Injury Compensation Programme (VICP) in Southeast Asian Countries

Around the world, various VICPs with various structures and methodologies are in use. Yet, the program works best when they are used with well-established, comprehensive, and balanced social assistance systems (Lookera & Kellya, 2011; Ericco *et al*., 2021). A survey by Mungwira *et al*. (2019) reports that the no-fault compensation program is not just implemented in high-income countries but the program are seen in China, Russia, and Thailand, the upper-middle-income countries; in Vietnam, the lower-middle-income country; and in Nepal, the low-income country. Nevertheless, global VICP differs significantly in structure. The viability of policy guidelines for countries to adopt is established by embracing these six standard features (administration and finance, eligibility, process, and decision-making, standard of proof, elements of compensation, and litigation rights) (Mungwira *et al*., 2020).

A Strategic Framework for the Southeast Asia Regional Vaccine Action Plan 2022–2030 was established to focus on ensuring and maintain the highest level of political and programmatic commitment and community acceptance for immunisation in the Southeast Asia Region in order to enable countries to achieve national and regional immunisation goals and targets (WHO, 2021d) Thus, 9 of the 11 countries with a programme similar to VICP have been established in Southeast Asia, 6 of which are included in the COVAX No-Fault Compensation Program for Advance Market Commitment (AMC) eligible economies while Malaysia, Singapore, and Thailand are governed by the government, as shown in Figure 2, which illustrates the adoption of VICP for the COVID-19 vaccines among Southeast Asian countries.

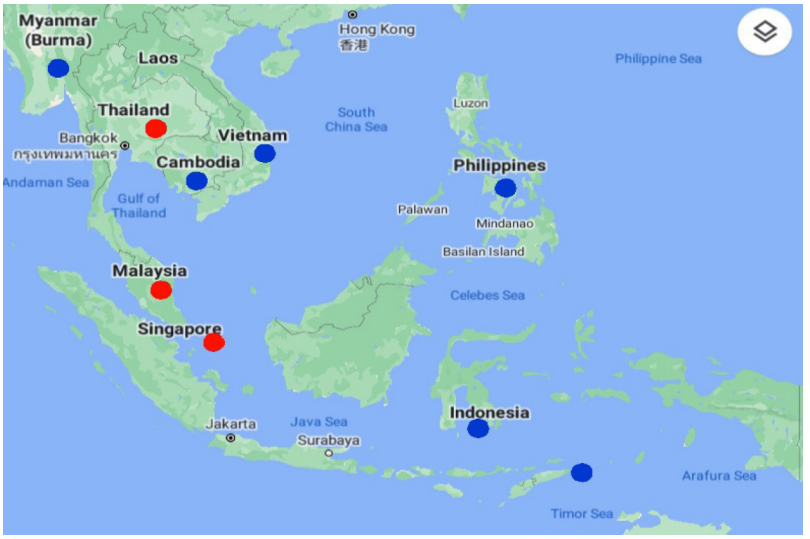

Figure 2: Southeast Asian countries that implement VICP for COVID-19 vaccines

i. Malaysia

In Malaysia, a unique financial assistance program is formed to help individuals develop serious AEFI of COVID-19 inoculations. The SFA program has the same concept as a no-fault system of VICP that compensates individuals who experience a rare vaccine-related injury due to the inherent risk of vaccination. It was launched on March 22, 2021, to compensate individuals up to RM500,000, and is applicable for those who develop serious AEFI that lead to disability or death. The Malaysian government believes that this program will assist in meeting the needs of vaccine recipients and their families due to of the effects of taking this vaccine (Malay Mail, 2021; NADMA, 2021). SFA for COVID-19 Vaccine Adverse Effects will be considered if the following criteria are met (JKJAV, 2021):

i. Serious Adverse Events Following Immunization (AEFI) must be classified as such based on the COVID-19 Vaccine Special Pharmacovigilance Committee's evaluation report;

ii. The AEFI report must be submitted to the National Pharmaceutical Regulatory Division (NPRA) by the health worker treating the patient;

iii. Serious AEFI must have occurred within three months of receiving the vaccine;

iv. In the event of death, the autopsy report must be attached; and evidence must be provided, as well as copies of pertinent papers;

v. Applications are only considered if submitted within 1 year from the date of occurrence of AEFI. Evidence and records of relevant documents should be submitted.

According to Dr. Adham Baba of the Ministry of Science, Technology and Innovation, a committee (COVID-19 Vaccine Harmful Effects of Special Financial Assistance Steering) has been formed for further evaluation and observation of the filed claims. The committee comprises the Pharmacovigilance Committee, which will monitor and assess adverse reactions following vaccination; the

Technical Committee, which will determine the authenticity of the assistance applicant; and the central committee, which will issue final permission for the particular aid. As of November 25, 2021, 8 of 93 claims were awarded for the SFA and the committee approved the total RM132,500, while 78 claims filed are still in process (Utusan Malaysia, 2021).

ii. Singapore

Vaccine Injury Financial Assistance Programme (VIFAP) offers one-time goodwill financial assistance to those who later developed serious side effects with COVID-19 vaccines under the National Vaccine Program (NVP). The amount of financial assistance offered is fixed and based on how severe the major side effect is. Pay-outs will be based on the greatest amount permitted and each person will only be qualified for one pay-out such as $225,000 for death and severe permanent impairment, regardless of hospitalisation or medical care. Serious AEFI include hospitalisation resulted in severe permanent impairment or was fatal. A medical professional must examine the serious AEFI to determine whether it is related to COVID-19 vaccines. The VIFAP does not accept COVID-19 immunizations obtained through the Private Vaccination Program and applications must be submitted no later than three years from the serious AEFI first appeared. It believes that VIFAP will provide more comfort to those receiving the vaccination (MOH, 2021c).

iii. Thailand

Thai citizens who receive vaccines and experience negative consequences after COVID-19 vaccination may file complaints on no-fault compensation for COVID-19 Vaccination's Adverse Events within two years of the onset of the side effects. This program is established under Section 41 of the 2002 National Health Security Act. The National Health Security Office (NHSO) regional offices, provincial health offices, or health units that administer COVID-19 vaccinations are all placed as committees to evaluate the applications. The maximum pay-outs fall into three categories, up to 100,000 baht for a prolong illness or injury, up to 240,000 baht for lost body parts or disabilities, and up to 400,000 baht for mortality or permanent disability. Five days after the panel receives complaints, the outcome will be released. Within 30 days of the release of the results, vaccine recipients can file an appeal with the NHSO secretary-general if they disagree with the decision (NHSO, 2021b).

iv. COVAX No-Fault Compensation Program

The recent COVID-19 pandemic has employed the international no-fault compensation system in the COVID-19 vaccine injury compensation scheme offered in 92 low-income and middle-income nations. The plan is the first and only vaccine injury compensation mechanism operating internationally. The purpose of the system is to provide qualified individuals with a fast, fair, robust, and transparent way to receive benefits for rare but serious adverse events associated with COVID-19 Vaccines Global Access (COVAX) distributed vaccines (WHO, 2021b). The scheme was signed by the World Health Organization (WHO) on behalf of the COVAX, which is co-led by the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance and the WHO, alongside the key delivery partner, United Nation Children's Fund (UNICEF) in order to safeguard the right of customers to file lawsuits in the case of a vaccine injury by agreements negotiation that offer vaccine manufacturers some level of liability protection (Berns, 2022).

A global compensation commission established at the COVAX Facility Centre that regularly monitors the COVID-19 vaccine landscape to find the best vaccination candidates relying on empirical merit and accessibility is a practical and feasible option that would expedite procurement of COVID-19 vaccinations. At the same time, it also ensures that vulnerable communities can seek compensation for injuries and establish a precedent for future vaccination campaigns (Halabi *et al*., 2020). The Program is available to all eligible individuals receiving a COVID-19 vaccine through the COVAX Facility and experienced a serious adverse

event that resulted in permanent impairment or death until 30 June 2023. Eligible individuals include citizens, residents, refugees, and other populations of concern (as defined by the Inter-Agency Standing Committee) in an AMC Eligible Economy which Cambodia, Indonesia, Myanmar, Timor-Leste, Vietnam, and the Philippines are included (WHO, 2022).

The Comparison of VICP among Southeast Asia

The compensation regime for COVID-19 vaccine injury can be described based on 6 key components: Administration and finance, eligibility, process and decision-making, the standard of proof, elements of compensation, and litigation rights. It can be seen that all of these critical components that are most used in existing VICP are covered in the no-fault system of VICP but with a different approach among the countries (Mungwira *et al*., 2020).

However, a no-fault system for COVID-19 vaccine injury is the first introduced by the Thailand government at the national level (NHSO, 2021a). Further, Myanmar, Cambodia, Timor-Leste, Indonesia, Vietnam, and the Philippines are the Southeast Asian countries that are included in the COVID-19 vaccine (COVAX) injury compensation scheme. Malaysia and Singapore have introduced their financial assistance program for COVID-19 vaccines. The key components of compensation regimes for COVID-vaccine injury related to vaccine injury in Southeast Asian are outlined in Table 2.

Table 2: The key components of compensation regimes for COVID-19 vaccine injury in Southeast Asian countries

Country	**Malaysia**	**Singapore**	**Thailand**	**Myanmar, Cambodia, Timor-Leste, Indonesia, Vietnam, and the Philippines**
Administrator	Ministry of Health, Malaysia (MOH)	Ministry of Health, Singapore (MOH)	National Health Security Office (NHSO)	ESIS, Inc.
Funding Source	Government	Government	Government	COVAX
Vaccine covered	COVID-19 vaccines offered by the government	COVID-19 vaccines offered by the government	COVID-19 vaccines provided by the government	COVAX-supplied vaccines
Eligibility: The injured party	Malaysian Citizen	Singapore citizen, permanent resident, or long-term pass-holder	Thailand citizens	92 low- and middle-income nations
Process and decision making	Medical Technical Committee of Ministry of Health	A clinical panel of the Ministry of Health	Sub-committee of NHSO	Nurses and physicians appointed by ESIS

Types of AEFI	Serious side effect (prolonged hospitalisation, death and permanent impairment)	Serious side effect (prolonged hospitalisation, death and permanent impairment)	Related or possibly related injury	Serious bodily injury (permanent impairment and death)
Timeframe for reporting	3 months after the incident and the claim must be submitted within 1 year	3 years after the incident	2 years after the incident	Incidents occur before June 2023
Relevant documentation	Assessment from the doctor and submit online form	Assessment from the doctor and submit online form	Compensation request form	Online application
Number of claims awarded/ Number of applicants	150/318 Update: June 7, 2023	413/not stated Update: January 27, 2023	9,551/12,882 Update: January 21, 2022	Not available
Right of Appeal	No	Not available	Yes	Not available
References	(NADMA, 2021; Rahim *et al*., 2023)	(MOH, 2021c; MOH, 2021b; The Straits Times, 2023)	(NHSO, 2021b; NHSO. 2022; Bangkok Post, 2021)	(Gavi, 2021)

As shown in Table 1, most VICP for damage caused by COVID-19 vaccines applied the same essential elements, but the approach depends on the administration or government. For example, Malaysia and Singapore seem to have strict proof for vaccine link to injury but not for Thailand, which is more flexible. All these components are based on the initiative from the government for affected individuals. However, the nation's acceptance of this programme is still lacking in the study. Thailand and Vietnam are the Southeast countries that have no-fault VICP before the outbreak of COVID-19 disease (Crum *et al*., 2021). In Malaysia, the types of injuries that have been awarded are not revealed by the administrator, similar as in Singapore. Applications need to be submitted within 1 year as opposed to 3 years in Singapore. As compared to Singapore and Thailand, Malaysia reported the lowest number of applicants with only 17% of the overall number of serious AEFI reported filed for the SFA as shown Figure 3.

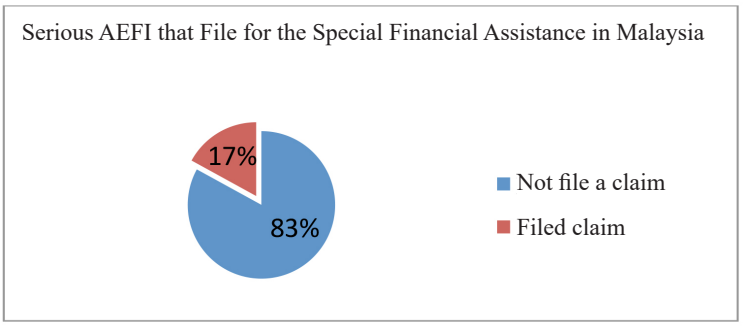

Figure 3: Percentages of serious AEFI that file SFA (Rahim *et al*., 2023)

From the data, the low number of reported claims compared to the severe AEFIs reported in Malaysia raises questions (Rahim *et al.,* 2023). This could be due to lack of awareness or the difficulty of the claims process. The same goes for the legal process. According to the Developing a Comprehensive National Vaccine Injury Compensation Program (NVICP) Research Report in the United State, parents and health care professionals were unaware that a federal vaccination harm compensation scheme exists. The study also found that most health care workers did not mention VICP during patient visits. Petitioners may also be under pressure to "settle" cases. According to NVICP, there are so few on-table compensable injuries stated and petitioners must prove causality for an off-table injury (HRSA, 2010).

Benefits of Vaccine Injury Compensation Programme

The most mentioned benefits in existing no-fault compensation programmes are them being more effective than the traditional legal system, fair compensation for those mistakenly damaged by vaccines for the social benefit, and reduced medical defence for physician context.

i. Litigation

If there is no established compensation scheme in place, the only way to get compensated is through the courts, usually done under tort law. A claimant must prove that they have been wronged due to another person's negligence or intentional harm under tort law. However, in the case of vaccination, the problem with the court-based compensation system is that there is frequently no negligent party. Further, a court-based compensation system can be inequitable and unexpected resulting in considerable financial compensation for some and no recompense for those who do not seek legal help (Lookera & Kellya, 2011; Halabi *et al*., 2020; Halabi, 2021).

In this sense, the VICP offers an advantage in overcoming the limitation of the court-based compensation system. Under the VICP, the injured party or their legal agent is not required to prove negligence or blame on the part of the vaccine provider which is health-care system or manufacturer. Although it pertains to tort law which is a strict liability system, the no-fault scheme is not based on fault. Without the need to prove negligence through a tort action, successful claims are paid in a standardized manner by utilizing a fixed benefits schedule and include compensation for both economic and non-economic (pain and suffering) losses (Nguyen, 2019). When compared to liability-based causes of action, implementing a no-fault vaccine injury compensation scheme is a desirable mechanism for compensating vaccination-related injuries since it provides a more efficient and accessible manner of accessing compensation. Table 3 compares VICP and the legal system for vaccine injury compensation. Hence, the timely introduction of no-fault vaccination injury compensation program should be at the forefront of politicians' reform agenda as vaccinations begin (Watts & Popa, 2021).

Table 3: The VICP and legal system are compared though tort law and the Consumer Protection Act 1999 in Malaysia jurisdiction

Categories	**Legal Process**		**VICP:SFA**
	Tort Law	**Consumer Protection Act 1999**	
Approach	Fault-based	Proof of product defect that link the injury	No-Fault based
Filing Deadline	Six years	Three years	One year (the injury must occur within three months after vaccination)
Right of Appeal	Yes	Yes	No

ii. Justice and Fairness

While a comprehensive no-fault compensation system may appear to be an appealing alternative to the tort or fault-based system, implementing such a change in our local context requires considerable thought (Kassim, 2014; Chuong *et al*., 2023). A no-fault system would also provide a better path to justice for patients who have suffered a medical injury including a more precise "road map" for obtaining appropriate compensation. Depending on the compensation criteria, level of compensation, and social context, no-fault systems have the ability to recompense many more patients than malpractice lawsuits and this need not result in a significant rise in cost (Douglas, 2009; Chuong *et al*., 2023). VICP that influences local context (social, population, political, and financial) must be considered for fairness and justice.

Many governments that have instituted compensation schemes have done to show solidarity among their citizens. According to ethicist Michelle Mello, it means that individuals of a community do not endure immunisation alone. Vaccine injuries can be serious and complex, and they are frequently experienced by children who require lifelong care and may be ineligible for other accident insurance coverage. The injured and undamaged pay disproportionate shares of the social cost of achieving the social good of herd immunity in a vaccination programme (Mello, 2008; Lookera & Kellya, 2011). Hence, VICP is considered more feasible for justice than the legal system.

iii. Social

A rise in patient understanding of their rights, a decline in professionalism among healthcare practitioners and changes in laws that have become more favourable and protective of patients have all driven medical malpractice litigation (Bateman, 2012; Halabi *et al*., 2022). While malpractice liability under the tort of law offers a social benefit, physicians see it differently. Doctors, know the malpractice lawsuit system as slow, ineffectual, and prejudiced against them (Kapp, 2016; Kapp & Reschovsky, 2018). Malpractice lawsuits are one of the most stressful aspects of being a doctor (Charles, 2001; Glassman & Lewis, 2022). In general, doctors' anxieties about the malpractice system are only tangentially related to the severity of their state's malpractice tort system and they frequently outweigh the risks. In the United States, physicians are more likely to practise defensive medicine at the highest malpractice risk. However, the number drops with the lowest malpractice risk.

Furthermore, while some believe that a physician's own malpractice experience influences their level of malpractice avoidance, studies have found that this is not the issue (Katz, 2019). The no-fault element of the programme decreases the high costs of medical malpractice insurance, diminishes the motivation to practise defensive medicine, and enhances flexibility in reporting unfavourable events from the perspective of medical practitioners. However, they lessen professional culpability for injury (Goodyear-Smith & Ashton, 2019; Wallis, 2013). By a no-fault system, a malpractice lawsuit may decrease the number, thus, reducing the defensive medicine among the physicians.

Challenges of Vaccine Injury Compensation Programme

Despite VICP seem to give benefits in term of justice compared to the legal system, the regulation has challenges due to its small scope of eligibility, complex administrative procedure, demanding standard of proof, and confusing compensation amount (Fei & Peng, 2017).

i. Limited Eligibility Requirements

Meeting eligibility rules is usually a prerequisite, and different countries have different approaches. As a result, it may limit access to justice under no-fault frameworks. For example, in Malaysia and Thailand, financial aid is only available to citizens of the country and is limited for the COVID-19 vaccines, while the Singapore aid is more accessible for injured parties. In another

context, to receive compensation under the VICP in the United States, injured party must adhere to the Vaccine Injury Table that include of vaccines, the injuries, disabilities, illnesses, conditions, and deaths (HRSA, 2021b). Other injuries that are out of the list need to be proved by medical investigation for the compensation claims. Thus, these limited eligibility requirements may limit access to justice under the no-fault frameworks. Eligibility may also be impacted by vaccination classification and the regulatory process. In contrast to vaccinations submitted under non-emergency circumstances, the data supporting vaccines regulated under the so-called "emergency procedure" is evaluated differently because risks and compensation may be considered differently (Halabi *et al*., 2022). Thus, these limited eligibility requirements may limit access to justice under the no-fault system.

ii. Demanding Standard of Proof

Serious Adverse Events Following Immunization (AEFI) must be classified as such based on the COVID-19 Vaccine Special Pharmacovigilance Committee's evaluation report. Thus, it means claimants suffering injuries not mentioned on the vaccine injury table must produce relevant medical reports or assessments which may include expert witness statements. According to Kelly *et al*. (2011), most worldwide compensation programmes follow the "balance of probability" method which considers that the vaccine caused the harm "more likely than not" based on the type of the injury, the consistency of the time interval from immunisation, the current medical data showing a link between the damage, and the vaccine, and other supporting information available (Kelly & Looker, 2011; Mugwira 2020). All of the programmes that were assessed by Mungwira *et al*. (2020) had to meet a certain level of proof that there was a causal link between vaccination and damage.

The question is whether claimants can prove a causal link between the injury and the vaccine as more than 65% of claims fail due to this causation hurdle under the United Kingdom's Vaccine Damage Payment Programme (Rajneri *et al*., 2018). An expert-led procedure that identifies cases where vaccination is connected to a specific adverse outcome could help prove causation (Fairgrieve *et al*., 2021).

For example, on September 25, an 18 years old girl was reported dead after 20 days of COVID 19 vaccine jab in Kedah and the director of Kedah State Health Department denied the death is related to vaccination as the post mortem result is due to rapture thoracic aortic aneurysm (Rahman, 2021). An abdominal aortic aneurysm, which is more common, happens below the chest as the walls of a blood artery become weakened, enlarges, or dilates, forming an aneurysm. Aneurysms can occur in every blood channel in the body but the aorta is the most common (Salameh *et al*., 2018).

This event raises controversy since the study reported by Luk *et al.* (2021) said that heart failure, myocardial injury/myocarditis, arrhythmia, and thromboembolism have all been documented as common cardiac consequences in adults after COVID-19 infection in multiple investigations. High death rates (51% - 97%) have been reported in various case series in people who develop myocarditis with raised inflammatory biomarkers (leukocytosis, lymphopenia, d-dimer, C-reactive proteins, and pro-calcitonin) and elevated troponin levels (Luk *et al*., 2021). Thus, the question arises why the case of the girl that died relation of heart disease is not considered to have link towards the vaccination even there is study that showed the connection of heart disease to COVID-19 vaccines.

iii. Time Limitation

In Malaysia, serious AEFI of COVID-19 vaccines must have occurred within 3 months of receiving the vaccines for file compensation. According to the Centers for Disease Control and Prevention (CDC), serious adverse effects that could lead to a long-term health concern are highly unlikely to occur after immunisation, including COVID-19. However, some vaccination-related impairment manifested years after the event and acknowledged by the Health and Human Service

(HHS) of the United States. HHS compensates for any individual who experiences AEFI that are included in the Vaccine Injury Table and acknowledges that some of the AEFI may develop after a year of vaccination (HRSA, 2021a).

In vaccine injury lawsuit in Italy, the Tribunal found a link between the child's vaccination in 2006 and autism in 2010, which came after the onset of various symptoms. This is because the court-appointed expert believed that the vaccine was more likely than any other conceivable cause to have caused the autism. First, samples of this vaccination appeared to contain mercury, which is hazardous to young children, according to an internal document from the vaccine manufacturer. Second, according to the internal paper, two incidences of autism were recorded out of more than 6 million people exposed to the vaccination over a 24-months period (Rajneri *et al*., 2018; Rizzi *et al*., 2021). For COVID-19 vaccines, they are relatively new and further study and surveys are needed to keep an eye on the significant point of AEFI.

Conclusion

Vaccination exposes individuals to the possibility of infrequent but severe side effects raising important considerations about vaccination liability and compensation. The issue of fair compensation for vaccine-related injuries has become more prominent, especially after the COVID-19 pandemic. The VICP is effective in compensating vaccine damage victims. However, it still has to be improved in terms of eligibility requirements, the standard of proof, and the time required for compensation for fairness. This is because there is no global standard level of serious adverse events eligible for compensation for COVID-19 vaccines. The findings of this study also show that VICP is effective in compensating vaccine damage victims compared to the traditional legal system. As shown in Table 2, Thailand, Malaysia, and Singapore use the term financial assistance programme instead of compensation which is possible due to their limited accountability. Nevertheless, they follow the components of the VICP worldwide but with limited criteria. However, there are some reservations about the program's effectiveness. Improvements are needed in terms of establishing criteria, proof standards, and the time required for satisfactory compensation. Therefore, governments should consider setting up dedicated teams or agencies to deal with compensation claims and ensure speedy resolution by expediting the application, review, and decision-making processes with fewer unnecessary delays. As a result, this study adds to the VICP's recognition in Southeast Asian countries, as well as its implementation in Malaysia. The ultimate aim is to strengthen existing processes in terms of accountability and compensation. Future research should look at whether the VICP or a comparable programme can satisfy victims and whether another alternative dispute resolution (ADR) method is better suited to solving this problem.

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